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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

Certified/Return Receipt Requested

April 29, 1998

WARNING LETTER

Dr. Steven P. Slagle, DVM
Owner/President
Animal Medical Center, Inc.
2222 Highway 169 North
Algona, IA 50511

Ref.# - KAN-98-016

Dear Dr. Slagle:

During an investigation of Farmland Industries' contract hog growing operation, located at the farms of Steven Reding and Jerel Kerber, Cylinder, Iowa, it was determined you provide their veterinary services. A Food and Drug Administration Investigator from this office documented deviations from Title 21, Code of Federal Regulations (21 CFR), Part 530, Extralabel Drug Use In Animals, which cause certain animal drugs used to medicate food producing animals, to be adulterated within the meaning of Section 501(a)(5) of the Federal Food, Drug, and Cosmetic Act (Act), in that they are new animal drugs which are unsafe within the meaning of Section 512(a)(4).

Furthermore, the investigation revealed that you failed to establish controls to assure that prescription veterinary drugs are sold only upon written or other order of a licensed veterinarian based upon a valid veterinarian/client/patient relationship. Such purchase, holding, and sale are serious violations of Sections 502(f)(1) and 503(f)(1) of the Act.

These prescription veterinary drugs are misbranded while held for sale after shipment in interstate commerce because they have lost their exemption from the requirement to bear adequate directions for use set forth under 21 CFR 201.105. These prescription veterinary drugs fail to bear adequate directions for use in accordance with Section 502(f)(1). Adequate directions for use means adequate directions for lay use. A prescription veterinary (animal) drug, one labeled "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian," is a drug which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary for its use is not safe for animal use except under the professional supervision of a licensed veterinarian and is a drug for which adequate directions for lay use cannot be written.

Prescription veterinary drugs are exempt from the statutory requirements for adequate directions for lay use only when they are in the possession of a person regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of drugs that are to be used by or on the prescription or order of a licensed veterinarian; or are in the possession of a retail, hospital, or clinic, or other person authorized under State law to dispense veterinary prescription drugs who is regularly and lawfully engaged in dispensing drugs that are to be used only by or on the prescription or other order of a licensed veterinarian in accordance with the regulations in 21 CFR 210.105 prescribed in Section 503(f)(1) of the Act.

Our investigation determined that Mr. Charles L. Groom, Swine Production Specialist for Farmland Industries regularly visits the two aforementioned contract hog growers, among others, to evaluate the confinement facilities and animals, and provide recommendations to the grower. These recommendations include the use of various drugs to improve the health of the animals. Mr. Groom is not a veterinarian. You then supply the recommended drugs upon request from the growers. There does not appear to be a valid veterinarian/client/patient relationship.

Based on the evaluations of the health conditions of pigs and/or hogs, Mr. Groom has recommended the use of several drug products, which you then supplied. Examples include:

PRESCRIPTION DRUGS (not approved for use in swine)

1. Tribrissen (actual drug used is Sulfatrim Pediatric Suspension, which is a human drug).
2. Cephalexin (a human drug).
3. Dexamethasone.
4. Gentamicin.

OVER-THE-COUNTER DRUGS (not approved for use in swine)

1. Long acting penicillin (Pen-G Procaine/Pen-G Benzathine).
2. LA200 (Oxytetracycline) which is approved for use in swine, but being recommended for use at dose levels above the labeled levels).

You are adulterating the above drugs which are dispensed for use on swine within the meaning of Section 501(a)(5) when you fail to use the drug in conformance with its approved labeling. Use of the drugs in a species for which they are not approved, or at a higher than labeled dosage, causes the drugs to be unsafe for use.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

In October of 1994, Congress passed the Animal Medicinal Drug Use Clarification Act, which permits extra-label use under certain controlled conditions, specified in 21 CFR Part 530. Extra label use is only permitted if the use is by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian/client/patient relationship and in conformance with criteria set forth in Part 530.

The violations listed above are not intended to be all inclusive. You, as a licensed veterinarian, have a responsibility to insure that all drugs intended for veterinary use, whether they bear the veterinary prescription legend "Caution: Federal law restricts this drug...", or are OTC, are dispensed or sold by you based upon a valid veterinarian/client/patient relationship.

A valid veterinarian/client/patient relationship, as defined by the American Veterinary Medical Association, is the following:

> An appropriate veterinarian/client/patient relationship, will exist when: (1) the veterinarian has assumed the responsibility for making medical judgements regarding the health of the animal(s) and the need for medical treatment, and the client (owner or other caretaker) has agreed to follow the instructions of the veterinarian; and when (2) there is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept; and when (3) the practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District

cc: Harry Cleberg, Chief Executive Officer
Farmland Industries
3315 North Oak Trafficway
P.O. Box 7305
Kansas City, MO 64116